REMARKS

Claims 1-2, 4-25 and 27-29 are pending in the application. Claims 1 and 11-25 have been canceled without prejudice or disclaimer. Claims 4-10, 27 and 29 have been amended to correct claim dependencies. These claims now depend from claim 2, which the Examiner noted was allowable (please see below). Support for the claim amendments can be found throughout the specification, and in the original claims as filed. No new matter has been entered by way of this amendment. Accordingly, claims 2, 4-10, and 27-29 are currently under consideration. Reconsideration of this application is respectfully requested.

Specification

The Examiner has objected to the disclosure because it contains an embedded hyperlink (page 6, paragraph [0014]). Applicants have amended paragraph [0014] on page 6 to delete the embedded hyperlink, and as such, withdrawal of the objection is respectfully requested.

Claim Objections

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

As follow-up to receipt of the Office Action, Applicants representative, Veronica Mallon, called Examiner Susan Beth McCormick-Ewoldt on September 25, 2006 to bring to her attention the fact that while the Examiner had noted in the Office Action that claim 2 was objected to, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims, claim 2 was already in independent form. The Examiner confirmed that it was an error and that claim 2 was already in independent and allowable format.

As such, Applicants have retained previously presented claim 2 as noted by the Examiner as being allowable, and have amended certain of the dependent claims to depend from claim 2 only.

Rejection under 35 U.S.C. §102

The Examiner has rejected claims 1, 5, 8 and 27-29 under 35 U.S.C. §102(a) anticipated by Khan, *et al.,* (Phytotherapy Research, Vol. 17, No. 2, pages 183-186, February 2003).

The Examiner's Position

The Examiner alleges that Khan, *et al.* teach a therapeutic (Pharmaceutical) composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds within the claimed concentration range (i.e., above 20% weight per volume) - see e.g. page 183, column 2, paragraph 2. The Examiner notes that "intended use" of a composition or product (e.g. treating hepatic disorders and/or increasing the number of immune cells) will not further limit claims drawn to a composition or product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants' Position

Applicants respectfully traverse the rejection and have canceled claim 1 and have amended claims 5, 8 and 27-29 to depend from claim 2, which as the Examiner noted (see above) is allowable as written. As such, Applicants assert that the rejection under 35 U.S.C. §102(a) is mooted and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103 (a)

The Examiner has rejected claims 1, 4-8 and 27-29 under 35 U.S.C. §103(a) as being unpatentable over Khan, *et al.*, (Phytotherapy Research, Vol. 17, No. 2, pages 183-186, February 2003).

The Examiner's Position

The Examiner alleges that Khan, *et al.* beneficially teach a therapeutic composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds

within the claimed concentration range (i.e. above 20% weight per volume) for effective use as an anti-fungal agent (see entire document including, e.g. page 183, column 2, paragraph 2).

The Examiner alleges that it would have been obvious to one of ordinary skill in the art the time the claimed invention was made to prepare a therapeutic pharmaceutical composition comprising a buffered aqueous extract of *Nigella sativa* (PBS extract) based upon the beneficial teachings provided by Khan, *et al.*, within a commonly employed delivery vehicle routinely used for such agents - such as within a tablet/capsule, suspension, spray, transdermal, suppository; and/or sterilizing such therapeutic composition for standard safety/shelf-life considerations and is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan having the cited reference before him/her.

The Examiner alleges that the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

The Examiner fails to set forth a proper *prima facie* case of obviousness

Applicants assert that a rejection under 35 U.S.C. §103 is proper only when a prior art reference alone or in combination with a second prior art reference renders the invention obvious. Applicants further assert that a rejection based upon a combination of references is not proper unless the following three criteria are met: 1) the references in combination teach every single element of the invention as claimed; 2) there must be some suggestion or motivation in the prior art to combine the references to reach the invention as claimed; and 3) there must be a reasonable expectation of success in making the combination to reach the invention as claimed.

Applicants' Invention as Claimed

As noted above, the present invention, as currently claimed, is directed to a pharmaceutical composition for treating a hepatic disorder and/or for increasing the number of immune cells and platelets in a patient consisting essentially of a therapeutically effective amount of a buffered aqueous extract of **Anemone hepatica and Nigella sativa**, and a pharmaceutically acceptable carrier, wherein the extract of Nigella sativa is present in a concentration of not less than 20% weight per volume. The composition may be delivered in the

form of a tablet, or capsule, or liquid suspension, or may be delivered intramuscularly, subcutaneously, intravenously, intranasally, topically, transdermally, or in the form of a suppository. The composition is effective for treating patients suffering from a hepatic disorder selected from the group consisting of chronic hepatitis, advanced/late stage hepatitis, hepatitis caused by hepatitis virus genotypes I, II, II or IV, a hepatic disorder characterized by fibrosis and/or cirrhosis, a hepatic disorder resulting from an autoimmune disease and a hepatic disorder resulting from a drug treatment. Treating patients with the composition results in modification of disease activity, including but not limited to, a decrease in hepatitis viral load, and a decrease in liver enzymes alanine aminotransferase (ALT) levels and aspartate aminotransferase (AST) levels.

Applicants Position Regarding Khan *et al.*

Applicants respectfully traverse the rejection and assert that Khan *et al.* do not teach or suggest the compositions of the present invention for treating a hepatic disorder or for increasing immune cell number as currently claimed, that is, a composition consisting essentially of a therapeutically effective amount of a buffered aqueous extract of **Anemone hepatica and Nigella sativa**, and a pharmaceutically acceptable carrier.

Furthermore, Khan *et al.* do not teach or suggest a pharmaceutical composition consisting essentially **of a buffered aqueous extract of Anemone hepatica and Nigella sativa** for treating a hepatic disorder selected from the group consisting of chronic hepatitis, advanced stage hepatitis, hepatitis caused by hepatitis virus genotypes I, II, II or IV, a hepatic disorder characterized by fibrosis and/or cirrhosis, a hepatic disorder resulting from an autoimmune disease and a hepatic disorder resulting from a drug treatment.

In addition, Khan *et al* do not teach or suggest a pharmaceutical composition consisting essentially **of a buffered aqueous extract of Anemone hepatica and Nigella sativa** for treating patients suffering from late stage liver disease characterized by fibrosis and cirrhosis, wherein treating with said composition results in modification of disease activity, including but not limited to, a decrease in hepatitis viral load, and a decrease in liver enzymes alanine aminotransferase (ALT) levels and aspartate aminotransferase (AST) levels.

Moreover, Applicants have canceled claim 1 and have amended claims 5, 8 and 27-29 to depend from claim 2, which, as the Examiner noted (see above), is allowable as written. As such, Applicants assert that the rejection under 35 U.S.C. §103(a) is mooted and withdrawal of the rejection is respectfully requested.

Fees

A check in the amount of $60.00 is included for the one month extension of time as a small entity. No other fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

Conclusion

Applicants believe that in view of the foregoing, the claims are in condition for allowance. Withdrawal of the rejections is respectfully requested. If a discussion with the undersigned will be of assistance in resolving any remaining issues, the Examiner is invited to telephone the undersigned at (201) 487-5800, ext. 118, to effect a resolution.

Respectfully submitted,

Veronica Mallon, Ph.D.
Agent for Applicants
Registration No. 52,491

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, NJ 07601
(201) 487-5800

Enclosures: Petition for a one month extension of time and a check for $60.00.